

APPENDIX A**Claim Charts**

Claim 17 of the '645 Patent	
Claim Language (Terms Potentially Requiring Construction in Bold)	PharmaStem's Proposed Construction and Evidence in Support
17. A pharmaceutical composition comprising	The preamble requires no construction.
(a) viable human neonatal or fetal hematopoietic stem cells derived from the umbilical cord or placental blood of a single human collected at the birth of said human,	<p>PROPOSED CONSTRUCTION: cells capable of effecting repopulation of blood and other hematopoietic organs.</p> <p>DICTIONARY/TREATISE DEFINITIONS: Webster's Dictionary (hematopoiesis: the making of blood; blood formation); Stedman's Medical Dictionary (hemopoietic: hematopoietic; hematoplastic; hemogenic; hemoplastic; sanguifacient; pertaining to or related to the formation of blood cells).</p> <p>INTRINSIC EVIDENCE: '645 Patent at col. 1:30-63 (The morphologically recognizable and functionally capable cells circulating in blood . . . derive from and are replaced, on demand, by morphologically recognizable dividing precursor cells for the respective lineages . . . The precursor cells derive from more primitive cells that can simplistically be divided into two major subgroups: stem cells and progenitor cells []. The definitions of stem and progenitor cells are operational and depend on functional, rather than on morphological, criteria. Stem cells have extensive self-renewal or self-maintenance capacity [], a necessity since absence or depletion of these cells could result in the complete depletion of one or more cell lineages, events that would lead within a short time to disease and death. Some of the stem cells differentiate upon need, but some stem cells or their daughter cells produce other stem cells to maintain the precious pool of these cells. Thus, in addition to maintaining their own kind, pluripotential stem cells are capable of differentiation into several sublines of progenitor cells with more limited self-renewal capacity or no self-renewal capacity. These progenitor cells ultimately give rise to the morphologically recognizable precursor cells.).</p>

	<p>EXTRINSIC EVIDENCE: Jury Instruction 3.2, in the litigation of the parent patents to the Patents-In-Suit⁴² ("hematopoietic stem cells" means "cells capable of effecting repopulation of blood and other hematopoietic organs"); ViaCord's "Frequently Asked Questions" website⁴³ (Cord blood, or umbilical cord blood, is the blood remaining in your child's umbilical cord following birth. It is a substance rich in stem cells, the building blocks of the blood and immune systems. Stem cells can divide to become other types of cells. The stem cells found in umbilical cord blood and bone marrow can divide and become red blood cells, white blood cells and platelets. They have been used as part of the treatment therapy in over 40 different cancers, immune deficiencies and genetic disorders.).</p>
<p>in which said cells are present in an amount sufficient to effect hematopoietic reconstitution of a human adult,</p>	<p>This claim term requires no construction. In Jury Instruction 3.2, in the litigation of the parent patents to the Patents-In-Suit, the entire phrase "[hematopoietic stem cells] in an amount sufficient to effect hematopoietic reconstitution of a human adult" was construed to mean "present in an amount that is as much as is needed to effect hematopoietic reconstitution of a human adult."⁴⁴ As can be seen from the prior claim construction, the term "in an amount sufficient" was given its plain meaning, while the term "hematopoietic reconstitution" was not construed at all.</p> <p>If the term "in an amount sufficient" or the term "hematopoietic reconstitution" requires construction, then PharmaStem proposes the following construction.</p> <p>PROPOSED CONSTRUCTION: in an amount that is as much as is needed to effect repopulation of a human adult's blood and other hematopoietic organs.</p> <p>DICTIONARY/TREATISE DEFINITIONS: Webster's Dictionary (sufficient: enough; equal to the end proposed; adequate to wants; as much as is needed); <i>Id.</i> (hematopoiesis: the making of blood; blood formation); <i>Id.</i> (reconstitution: the act of re-forming, or forming anew; a restoration); Stedman's Medical Dictionary</p>

⁴² See Little Decl., Exh. 7, at page 15.

⁴³ See Little Decl., Exh. 31, at page 1.

⁴⁴ See Little Decl., Exh. 7, at page 15.

	<p>(hemopoietic; hematopoietic; hematoplastic; hemogenic; hemoplastic; sanguifacient; pertaining to or related to the formation of blood cells).</p> <p>INTRINSIC EVIDENCE: '645 Patent at col. 11:55 to col. 12:20 ("In a preferred embodiment, volumes of 50 ml or more of neonatal blood are obtained. . . . The [] information suggests that as little as 50 ml of cord blood contains enough of the appropriate cells to repopulate the hematopoietic system of an adult, and it is possible that even less cord blood would have the same effect."); '645 Patent at col. 2:65 to col. 3:16 (Reconstitution of the hematopoietic system has been accomplished by bone marrow transplantation. . . Thus, stem and progenitor cells in donated bone marrow can multiply and replace the blood cells responsible for protective immunity, tissue repair, clotting, and other function of the blood. In a successful bone marrow transplantation, the blood, bone marrow, spleen, thymus and other organs of immunity are repopulated with cells derived from the donor.); '645 Patent at col. 23:60 to col. 24:3 (The neonatal hematopoietic stem and progenitor cells of the present invention can be used therapeutically for hematopoietic reconstitution, with either syngeneic or allogeneic hosts. The neonatal cells can be introduced into a patient for repopulation of the blood and other hematopoietic organs in the treatment or prevention of various diseases or disorders . . .).</p> <p>EXTRINSIC EVIDENCE: Jury Instruction 3.2, in the litigation of the parent patents to the Patents-In-Suit⁴⁵ ("[hematopoietic stem cells] in an amount sufficient to effect hematopoietic reconstitution of a human adult" means "present in an amount that is as much as is needed to effect hematopoietic reconstitution of a human adult."); ViaCord's "Frequently Asked Questions" website⁴⁶ (The stem cells found in umbilical cord blood and bone marrow can divide and become red blood cells, white blood cells and platelets. They have been used as part of the treatment therapy in over 40 different cancers, immune deficiencies and genetic disorders. . . Stem cells are used therapeutically for their ability to help restore function to the blood-making and immune systems.).</p>
--	--

⁴⁵ See Little Decl., Exh. 7, at page 15.

⁴⁶ See Little Decl., Exh. 31, at page 1.

<p>which cells have been cryopreserved; and</p>	<p>This claim term requires no construction. If the term "cryopreserved" requires construction, then PharmaStem offers the following construction.</p> <p>PROPOSED CONSTRUCTION: stored at very low temperatures.</p> <p>DICTIONARY/TREATISE DEFINITIONS: Stedman's Medical Dictionary (cryopreservation: Maintenance of the viability of the excised tissues or organs at extremely low temperatures).</p> <p>INTRINSIC EVIDENCE: '645 Patent at col. 20:10-22 (The freezing of cells is ordinarily destructive, on cooling, water within the cell freezes. Injury then occurs by osmotic effects on the cell membrane, cell dehydration, solute concentration, and ice crystal formation. . . These injurious effects can be circumvented by (a) use of a cryoprotective agent, (b) control of the freezing rate, and (c) storage at a temperature sufficiently low to minimize degradative reactions.).</p>
<p>(b) a pharmaceutically acceptable carrier.</p>	<p>This claim term requires no construction. If the term "pharmaceutically acceptable carrier" requires construction, then PharmaStem offers the following construction.</p> <p>PROPOSED CONSTRUCTION: any medically acceptable carrier, including but not limited to saline, buffered saline, dextrose and water.</p> <p>DICTIONARY/TREATISE DEFINITIONS: Webster's Dictionary (pharmaceutical: of pharmacy; pharmacy: the art or profession of preparing, preserving, and compounding medicines and drugs and of dispensing them according to the prescriptions of physicians).</p> <p>INTRINSIC EVIDENCE: '645 Patent at col. 24:14-19 (The present invention provides pharmaceutical compositions comprising the neonatal stem and progenitor cells of the invention, which have been cryopreserved, and a pharmaceutically acceptable carrier. Such carriers include any sterile biocompatible pharmaceutical carrier, including but not limited to saline, buffered saline, dextrose and water.).</p>

Claim 46 of the '427 Patent	
Claim Language (Terms Potentially Requiring Construction in Bold)	PharmaStem's Proposed Construction and Evidence in Support
46. A method for treating a human patient in need of hematopoietic reconstitution comprising	The preamble requires no construction or should be construed consistently with the terms below.
introducing into the human patient	This claim term requires no construction.
a composition comprising human neonatal or fetal hematopoietic stem cells derived from the umbilical cord blood or placental blood of a human collected at birth of said human,	<p>PROPOSED CONSTRUCTION: cells capable of effecting repopulation of blood and other hematopoietic organs.</p> <p>DICTIONARY/TREATISE DEFINITIONS: Webster's Dictionary (hematopoiesis: the making of blood; blood formation); Stedman's Medical Dictionary (hemopoietic: hematopoietic; hematoplastic; hemogenic; hemoplastic; sanguifacient; pertaining to or related to the formation of blood cells).</p> <p>INTRINSIC EVIDENCE: '427 Patent at col. 3:15-48 (The morphologically recognizable and functionally capable cells circulating in blood . . . derive from and are replaced, on demand, by morphologically recognizable dividing precursor cells for the respective lineages . . . The precursor cells derive from more primitive cells that can simplistically be divided into two major subgroups: stem cells and progenitor cells []. The definitions of stem and progenitor cells are operational and depend on functional, rather than on morphological, criteria. Stem cells have extensive self-renewal or self-maintenance capacity [], a necessity since absence or depletion of these cells could result in the complete depletion of one or more cell lineages, events that would lead within a short time to disease and death. Some of the stem cells differentiate upon need, but some stem cells or their daughter cells produce other stem cells to maintain the precious pool of these cells. Thus, in addition to maintaining their own kind, pluripotential stem cells are capable of differentiation into several sublines of progenitor cells with more limited self-renewal capacity or no self-renewal capacity. These progenitor cells ultimately give rise to the morphologically recognizable precursor cells.).</p>

	<p>EXTRINSIC EVIDENCE: Jury Instruction 3.2, in the litigation of the parent patents to the Patents-In-Suit⁴⁷ ("hematopoietic stem cells" means "cells capable of effecting repopulation of blood and other hematopoietic organs"); ViaCord's "Frequently Asked Questions" website⁴⁸ (Cord blood, or umbilical cord blood, is the blood remaining in your child's umbilical cord following birth. It is a substance rich in stem cells, the building blocks of the blood and immune systems. Stem cells can divide to become other types of cells. The stem cells found in umbilical cord blood and bone marrow can divide and become red blood cells, white blood cells and platelets. They have been used as part of the treatment therapy in over 40 different cancers, immune deficiencies and genetic disorders.).</p>
in which the stem cells have been previously cryopreserved ,	<p>This claim term requires no construction. If the term "cryopreserved" requires construction, then PharmaStem offers the following construction.</p> <p>PROPOSED CONSTRUCTION: stored at very low temperatures.</p> <p>DICTIONARY/TREATISE DEFINITIONS: Stedman's Medical Dictionary (cryopreservation: Maintenance of the viability of the excised tissues or organs at extremely low temperatures).</p> <p>INTRINSIC EVIDENCE: '427 Patent at col. 21:63 to col. 22:8 (The freezing of cells is ordinarily destructive, on cooling, water within the cell freezes. Injury then occurs by osmotic effects on the cell membrane, cell dehydration, solute concentration, and ice crystal formation. . . These injurious effects can be circumvented by (a) use of a cryoprotective agent, (b) control of the freezing rate, and (c) storage at a temperature sufficiently low to minimize degradative reactions.).</p>
so as to provide hematopoietic reconstitution .	<p>This claim term requires no construction. If the term "hematopoietic reconstitution" requires construction, then PharmaStem proposes the following construction.</p> <p>PROPOSED CONSTRUCTION: repopulation of a human patient's blood and other hematopoietic organs.</p>

⁴⁷ See Little Decl., Exh. 7, at page 15.

⁴⁸ See Little Decl., Exh. 31, at page 1.

	<p>DICTIONARY/TREATISE DEFINITIONS: Webster's Dictionary (hematopoiesis: the making of blood; blood formation); Stedman's Medical Dictionary (hemopoietic: hematopoietic; hematoplastic; hemogenic; hemoplastic; sanguifacient; pertaining to or related to the formation of blood cells); Webster's Dictionary (reconstitution: the act of re-forming, or forming anew; a restoration).</p> <p>INTRINSIC EVIDENCE: '427 Patent at col. 4:52 to col. 5:2 (Reconstitution of the hematopoietic system has been accomplished by bone marrow transplantation. . . Thus, stem and progenitor cells in donated bone marrow can multiply and replace the blood cells responsible for protective immunity, tissue repair, clotting, and other function of the blood. In a successful bone marrow transplantation, the blood, bone marrow, spleen, thymus and other organs of immunity are repopulated with cells derived from the donor.); '427 Patent at col. 25:37-45 (The neonatal hematopoietic stem and progenitor cells of the present invention can be used therapeutically for hematopoietic reconstitution, with either syngeneic or allogeneic hosts. The neonatal cells can be introduced into a patient for repopulation of the blood and other hematopoietic organs in the treatment or prevention of various diseases or disorders . . .).</p> <p>EXTRINSIC EVIDENCE: ViaCord's "Frequently Asked Questions" website⁴⁹ (The stem cells found in umbilical cord blood and bone marrow can divide and become red blood cells, white blood cells and platelets. They have been used as part of the treatment therapy in over 40 different cancers, immune deficiencies and genetic disorders. . . Stem cells are used therapeutically for their ability to help restore function to the blood-making and immune systems.).</p>
--	---

Claim 49 of the '427 Patent	
Claim Language (Terms Potentially Requiring Construction in Bold)	PharmaStem's Proposed Construction and Evidence in Support

⁴⁹ See Little Decl., Exh. 31, at page 1.

A method for storing human neonatal or fetal hematopoietic stem cells derived from the blood, said method comprising	The preamble requires no construction or should be construed consistently with the terms below.
cryopreserving human neonatal or fetal blood components	<p>This claim term requires no construction. If the term "cryopreserving" requires construction, then PharmaStem offers the following construction.</p> <p>PROPOSED CONSTRUCTION: storing at very low temperatures. (Same as Claim 46 of the '427 Patent.)</p>
containing human neonatal or fetal hematopoietic stem cells from the umbilical cord blood or placental blood of a single human collected at the birth of said human, such that the cells remain viable,	PROPOSED CONSTRUCTION: cells capable of effecting repopulation of blood and other hematopoietic organs. (Same as Claim 46 of the '427 Patent.)
in which said cells are present in an amount sufficient to effect hematopoietic reconstitution of a human adult .	<p>This claim term requires no construction. In Jury Instruction 3.2, in the litigation of the parent patents to the Patents-In-Suit, the entire phrase "[hematopoietic stem cells] in an amount sufficient to effect hematopoietic reconstitution of a human adult" was construed to mean "present in an amount that is as much as is needed to effect hematopoietic reconstitution of a human adult."⁵⁰ As can be seen from the prior claim construction, the term "in an amount sufficient" was given its plain meaning, while the term "hematopoietic reconstitution" was not construed at all.</p> <p>If the term "in an amount sufficient" or the term "hematopoietic reconstitution" requires construction, then PharmaStem proposes the following construction.</p> <p>PROPOSED CONSTRUCTION: in an amount that is as much as is needed to effect repopulation of a human adult's blood and other hematopoietic organs.</p> <p>DICTIONARY/TREATISE DEFINITIONS: Webster's Dictionary (sufficient: enough; equal to the end proposed; adequate to wants; as much as is needed); <i>Id.</i> (hematopoiesis: the making of blood; blood formation); <i>Id.</i> (reconstitution: the act of re-forming, or forming anew; a restoration); Stedman's Medical Dictionary (hemopoietic: hematopoietic; hematoplastic; hemogenic;</p>

⁵⁰ See Little Decl., Exh. 7, at page 15.

	<p>hemoplastic; sanguifacient; pertaining to or related to the formation of blood cells).</p> <p>INTRINSIC EVIDENCE: '427 Patent at col. 13:32-45 ("In a preferred embodiment, volumes of 50 ml or more of neonatal blood are obtained. . . . The [] information suggests that as little as 50 ml of cord blood contains enough of the appropriate cells to repopulate the hematopoietic system of an adult, and it is possible that even less cord blood would have the same effect."); '427 Patent at col. 4:52 to col. 5:2 (Reconstitution of the hematopoietic system has been accomplished by bone marrow transplantation. . . Thus, stem and progenitor cells in donated bone marrow can multiply and replace the blood cells responsible for protective immunity, tissue repair, clotting, and other function of the blood. In a successful bone marrow transplantation, the blood, bone marrow, spleen, thymus and other organs of immunity are repopulated with cells derived from the donor.); '427 Patent at col. 25:37-45 (The neonatal hematopoietic stem and progenitor cells of the present invention can be used therapeutically for hematopoietic reconstitution, with either syngeneic or allogeneic hosts. The neonatal cells can be introduced into a patient for repopulation of the blood and other hematopoietic organs in the treatment or prevention of various diseases or disorders . . .).</p> <p>EXTRINSIC EVIDENCE: Jury Instruction 3.2, in the litigation of the parent patents to the Patents-In-Suit⁵¹ ("[hematopoietic stem cells] in an amount sufficient to effect hematopoietic reconstitution of a human adult" means "present in an amount that is as much as is needed to effect hematopoietic reconstitution of a human adult."); ViaCord's "Frequently Asked Questions" website⁵² (The stem cells found in umbilical cord blood and bone marrow can divide and become red blood cells, white blood cells and platelets. They have been used as part of the treatment therapy in over 40 different cancers, immune deficiencies and genetic disorders. . . Stem cells are used therapeutically for their ability to help restore function to the blood-making and immune systems.).</p>
--	---

⁵¹ See Little Decl., Exh. 7, at page 15.

⁵² See Little Decl., Exh. 31, at page 1.

APPENDIX B**Infringement Charts:**

Claim 17 of the '645 Patent	
Claim (Elements in Bold)	Infringement Evidence
17. A pharmaceutical composition comprising (a) viable	<p><u>ViaCell Statements:</u></p> <p>"How long can cord blood stem cells be stored? Scientific research has yet to determine the actual length of time these cells can be stored and still be viable. It is known that cord blood stem cells remain viable for many years and possibly decades. So far, the longest time bone marrow stem cells have been frozen and successfully transplanted was eleven years as reported by Dr. Joe Antin in Bone Marrow Transplantation in 1992. Dr. Peter Kobylka of the University of Amsterdam showed viability of cord blood stem cells frozen for 15 years."⁵³</p> <p>"In the event that your cord blood unit is needed for transplant, Viacord will conduct appropriate testing on both the cord and maternal blood samples and ship the cord blood unit to the appropriate facility upon written request from a physician qualified to perform a stem cell transplant."⁵⁴</p> <p>"How many samples have been used for transplant from Viacord? Did they all engraft? Eleven of our banked units have been used in transplant—all have successfully engrafted."⁵⁵</p>
human neonatal or fetal hematopoietic stem cells	<p><u>ViaCell Statements:</u></p> <p>"In the early 1980s, Dr. Hal Broxmeyer (now a member of Viacord's Medical Scientific Advisory Board) was instrumental in validating that the blood remaining in the umbilical cord after birth is rich in a precious resource called stem cells. Stem cells are the building blocks of our blood and immune systems and, potentially, the nervous system, skin, bones, heart, endocrine organs and other body tissue. Over the past decade, thousands of cord blood stem cell transplants have been successfully performed worldwide."⁵⁶</p> <p>"Your pregnancy provides an opportunity to do something extraordinary for your baby and your entire family. By choosing to preserve your newborn's cord blood with Viacord, you will preserve your family's chance to potentially use it as part of a treatment therapy</p>

⁵³ See Little Decl., Exh. 13, at page 3.

⁵⁴ See Little Decl., Exh. 9, at § 1.

⁵⁵ See Little Decl., Exh. 16, at page 3.

⁵⁶ See Little Decl., Exh. 10.

	<p>for over 40 diseases, including various cancers, genetic diseases, blood disorders and immune system deficiencies."⁵⁷</p> <p>"Umbilical cord blood offers a perfectly natural, controversy-free method of acquiring stem cells. (Even the Pope approves of cord blood banking.) Cord blood offers several advantages over other methods. It's collected in a safe, 5-minute procedure after a baby is born and is painless for both mother and baby. Also, cord blood transplants have a significantly lower rate of graft vs. host disease than bone marrow transplants. Plus, cord blood stem cells are a perfect match for the baby and can potentially be used to treat siblings and other family members as well. . . In April of 1995, a 32-year-old man from the Netherlands received the most precious gift of all from his newborn daughter. It was the gift of life. After years of continuous struggle with leukemia, the young father preserved his newborn's cord blood stem cells, which in turn were used to treat his life- threatening disease. This was perhaps one of the most extraordinary gifts ever exchanged between a father and a daughter. Not to mention, a true testament of the power of cord blood."⁵⁸</p>
<p>derived from the umbilical cord or placental blood of a single human collected at the birth of said human,</p>	<p><u>ViaCell Statements:</u></p> <p>"Your pregnancy provides an opportunity to do something extraordinary for your baby and your entire family. By choosing to preserve your newborn's cord blood with Viacord, you will preserve your family's chance to potentially use it as part of a treatment therapy for over 40 diseases, including various cancers, genetic diseases, blood disorders and immune system deficiencies."⁵⁹</p> <p>"(Step 1:) Once you have enrolled, you will receive a collection kit to take with you to the hospital when you are ready to deliver. We will also provide your doctor with the materials and training needed for the cord blood collection. (Step 2:) Upon arriving at the hospital, give Viacord's 24-hour on-call service a call so we can review the collection process with your doctor or nurse. . . (Step 3:) After delivering your newborn, your doctor clamps and cuts the umbilical cord then takes your baby out of the birthing area. The collection itself is simple, aseptic, painless and does not interfere with your delivery. . . (Step 4:) Once you've called Viacord to let us know the cord blood was collected, Viacord arranges for a private medical courier to bring your baby's cord blood unit to the nearest airport where it is put on the next flight out to our state-of-the-art long-term storage facility. . . (Step 5:) Upon receipt of your baby's cord blood unit our storage facility conducts the following tests on the cord blood</p>

⁵⁷ See Little Decl., Exh. 11.

⁵⁸ See Little Decl., Exh. 15.

⁵⁹ See Little Decl., Exh. 11.

	sample that are essential in the event of a potential transplant: the volume collected, the number and viability of nucleated cells, sterility, and the percent of CD34 cells. . . (Step 6:) After testing, your baby's cord blood unit is cryopreserved in cryoprotected blood bags at -196 degrees Celsius (-321 degrees Fahrenheit). . ."60
in which said cells are present in an amount sufficient to effect hematopoietic reconstitution of a human adult,	<p><u>ViaCell's Statements:</u> "Your baby's cord blood could someday save a life. Your baby's. Your family's. Yours."⁶¹</p> <p>"Cord blood stem cells are a perfect match for your baby, have a high probability of being a viable match for a sibling and can be potentially be used for parents and grandparents in the treatment of over 40 diseases including a wide range of cancers, genetic diseases, immune system deficiencies and blood disorders."⁶²</p> <p>"Umbilical cord blood offers a perfectly natural, controversy-free method of acquiring stem cells. (Even the Pope approves of cord blood banking.) Cord blood offers several advantages over other methods. It's collected in a safe, 5-minute procedure after a baby is born and is painless for both mother and baby. Also, cord blood transplants have a significantly lower rate of graft vs. host disease than bone marrow transplants. Plus, cord blood stem cells are a perfect match for the baby and can potentially be used to treat siblings and other family members as well. . . In April of 1995, a 32-year-old man from the Netherlands received the most precious gift of all from his newborn daughter. It was the gift of life. After years of continuous struggle with leukemia, the young father preserved his newborn's cord blood stem cells, which in turn were used to treat his life- threatening disease. This was perhaps one of the most extraordinary gifts ever exchanged between a father and a daughter. Not to mention, a true testament of the power of cord blood."⁶³</p> <p><u>ViaCell's Quality Product Guarantee:</u> "If the cord blood stem cells processed and stored by Viacord are used in a hematopoietic stem cell transplant following standard, recognized medical practices and they do not engraft, Viacord will pay \$25,000 to the legal owner of the cells per the Viacord Enrollment Agreement."⁶⁴ (Notably, ViaCell's guarantee explicitly includes transplants to the biological parents of the donor, so long as, the transplanted cord blood does not contain less than 2×10^7 total nucleated cells per kilogram or</p>

⁶⁰ See Little Decl., Exh. 12, *passim*.

⁶¹ See Little Decl., Exh. 14.

⁶² See Little Decl., Exh. 14.

⁶³ See Little Decl., Exh. 15.

⁶⁴ See Little Decl., Exh. 9, at last two pages.

	<p>less than 1×10^5 CD34+ cells per kilogram, is not co-transplanted with supplemental stem cell sources (e.g., additional cord blood, peripheral blood or bone marrow), and does not use experimental procedures, such as, stem cell expansion.⁶⁵ Thus, so long as the adult patient is a biological parent of the donor and the transplanted cord blood contains at least 2×10^7 total nucleated cells per kilogram and 1×10^5 CD34+ cells per kilogram, if the cord blood does not engraft in the adult patient following a standard transplantation procedure, ViaCell is bound by its Quality Product Guarantee.)</p> <p><u>ViaCell Actual Transplants:</u> "How many samples have been used for transplant from Viacord? Did they all engraft?" Eleven of our banked units have been used in transplant—all have successfully engrafted."⁶⁶</p> <p><u>Scientific Journal Articles/Studies (internal citations omitted):</u> Harris, D. T., <i>Cord Blood Banking and Its Potential Clinical Applications</i>. "[Q]uestions have been raised as to whether cord blood transplantation would ever be suitable for adult use, or restricted to use in children. To date, the smallest amount of cord blood ever used in a successful transplant has been 43 cc, and the largest patient ever successfully transplanted is now 85 kg. Thus, it appears that a typical cord blood collection is of sufficient size for use in almost all transplant conditions."</p> <p>Laughlin, M. J., et al., <i>Hematopoietic Engraftment And Survival In Adult Recipients Of Umbilical-Cord Blood From Unrelated Donors</i>, New England Journal of Medicine (2001)("Laughlin"). <i>"In summary, the results of this study demonstrate that HLA-mismatched umbilical-cord blood from unrelated donors is a feasible alternative source of hematopoietic stem cells for transplantation in adults."</i></p> <p><i>Umbilical Cord Stem Cell Transplants Should Not Be Limited By Age</i>, The Blue Sheet (Food and Drug Administration), March 5, 2003 ("FDA Blue Sheet"). <i>"Placental cord blood transplant recipient age should not be a factor."</i></p> <p>Sanz, G. F., et al., <i>Standardized, Unrelated Donor Cord Blood Transplantation in Adults with Hematologic Malignancies</i>, Blood (2001)("Sanz"). "[Cord blood transplantation], despite the low cellular dose infused, is</p>
--	---

⁶⁵ See Little Decl., Exh. 9, at last page.

⁶⁶ See Little Decl., Exh. 16, at page 3.

	<p>capable of promoting sustained hematopoietic engraftment in most adult recipients."</p> <p>Gluckman, E., <i>Current Status of Umbilical Cord Blood Hematopoietic Stem Cell Transplantation</i>, Experimental Hematology (2000)("Gluckman"). "[R]esults show that [cord blood transplantation] can be a good option for adults."</p> <p>Iseki, T., <i>et al.</i>, <i>Unrelated Cord Blood Transplantation in Adults with Hematological Malignancy: A Single Institution Experience</i>, Blood Abstract #2789 (2000)("Iseki"). "[Cord blood transplantation in adults] was comparable to that of standard bone marrow transplantation."</p> <p>Ooi, J., <i>et al.</i>, <i>Unrelated Cord Blood Transplantation for Adults Patients with Advanced Myelodysplastic Syndrome</i>, Blood (2003)("Ooi I"). "[Adult patients] should be considered candidates for [cord blood transplants]."</p> <p>Ooi, J., <i>et al.</i>, <i>Unrelated Cord Blood Transplantation for Adults Patients with De Novo Acute Myeloid Leukemia</i>, Blood (2004)("Ooi II"). (Same as Ooi I.)</p> <p>Long, G. D., <i>et al.</i>, <i>Unrelated Cord Blood Transplantation in Adults Patients</i>, Biology of Blood and Marrow Transplantation (2003)("Long"). "These results suggest that unrelated umbilical cord blood transplantation is a viable option for adult patients."</p> <p>Koh, L-P, <i>et al.</i>, <i>Umbilical Cord Blood Transplantation in Adults Using Myeloablative and Nonmyeloablative Preparative Regimens</i>, Biology of Blood and Marrow Transplantation (2004)("Koh"). "The concern of limited doses leading to a higher risk of primary graft failure in adults is related to the disproportionate difference between the number of nucleated cells in the [umbilical cord blood] graft and the adult body weight, giving rise to relative fewer infused cells per kilogram of the recipient body weight, especially in heavier patients. However, the available data on adult recipients of unrelated [umbilical cord blood transplants] thus far have shown the [umbilical cord blood] contained sufficient numbers of hematopoietic stem cells to achieve engraftment."</p> <p>Moscardo, F., <i>et al.</i>, <i>Unrelated-Donor Cord Blood Transplantation for</i></p>
--	---

	<p><i>Adult Hematological Malignancies, Leukemia & Lymphoma</i> (2004)("Moscardo").</p> <p>"The reported data show that, contrary to initial concerns, [cord blood transplants] can promote engraftment in the majority of adult patients."</p> <p>Barker, J. N., <i>et al.</i>, <i>Rapid and Complete Donor Chimerism in Adult Recipients of Unrelated Donor Umbilical Cord Blood Transplantation After Reduced-Intensity Conditioning</i>, Blood (2003)("Barker").</p> <p>"[The] data demonstrates that 0-2 antigen mismatched [umbilical cord blood] is sufficient to engraft most adults after reduced-intensity conditioning."</p>
which cells have been cryopreserved ; and	<p><u>ViaCell Statements:</u></p> <p>"(Step 1:) Once you have enrolled, you will receive a collection kit to take with you to the hospital when you are ready to deliver. We will also provide your doctor with the materials and training needed for the cord blood collection. (Step 2:) Upon arriving at the hospital, give Viacord's 24-hour on-call service a call so we can review the collection process with your doctor or nurse. . . (Step 3:) After delivering your newborn, your doctor clamps and cuts the umbilical cord then takes your baby out of the birthing area. The collection itself is simple, aseptic, painless and does not interfere with your delivery. . . (Step 4:) Once you've called Viacord to let us know the cord blood was collected, Viacord arranges for a private medical courier to bring your baby's cord blood unit to the nearest airport where it is put on the next flight out to our state-of-the-art long-term storage facility. . . (Step 5:) Upon receipt of your baby's cord blood unit our storage facility conducts the following tests on the cord blood sample that are essential in the event of a potential transplant: the volume collected, the number and viability of nucleated cells, sterility, and the percent of CD34 cells. . . (Step 6:) After testing, your baby's cord blood unit is cryopreserved in cryoprotected blood bags at -196 degrees Celsius (-321 degrees Fahrenheit). . ."⁶⁷</p>
(b) a pharmaceutically acceptable carrier .	<p>While ViaCell most likely uses anticoagulants, the use of which will likely be discovered, at the very least, it is known that ViaCell (1) adjusts the volume of its cord blood units with plasma if the pre-processing weight is less than 45 grams and (2) always uses the cryoprotectant DMSO, diluted to 10%, and a cell media called RPMI, diluted to 10%.⁶⁸ Anticoagulant, anticoagulant dilutant, plasma, DMSO, DMSO dilutant, RPMI, and RPMI dilutant each constitute pharmaceutically acceptable carriers.</p>
Claim 46 of the '427 Patent	
Claim (Elements in	Infringement Evidence

⁶⁷ See Little Decl., Exh. 12, *passim*.

⁶⁸ See Little Decl., Exh. 30, at page 2.

Bold)	
<p>46. A method for treating a human patient in need of hematopoietic reconstitution comprising introducing into the human patient</p>	<p><u>ViaCell Statements:</u></p> <p>"In the early 1980s, Dr. Hal Broxmeyer (now a member of Viacord's Medical Scientific Advisory Board) was instrumental in validating that the blood remaining in the umbilical cord after birth is rich in a precious resource called stem cells. Stem cells are the building blocks of our blood and immune systems and, potentially, the nervous system, skin, bones, heart, endocrine organs and other body tissue. Over the past decade, thousands of cord blood stem cell transplants have been successfully performed worldwide."⁶⁹</p> <p>"In the event that your cord blood unit is needed for transplant, Viacord will conduct appropriate testing on both the cord and maternal blood samples and ship the cord blood unit to the appropriate facility upon written request from a physician qualified to perform a stem cell transplant."⁷⁰</p> <p>"Umbilical cord blood offers a perfectly natural, controversy-free method of acquiring stem cells. (Even the Pope approves of cord blood banking.) Cord blood offers several advantages over other methods. It's collected in a safe, 5-minute procedure after a baby is born and is painless for both mother and baby. Also, cord blood transplants have a significantly lower rate of graft vs. host disease than bone marrow transplants. Plus, cord blood stem cells are a perfect match for the baby and can potentially be used to treat siblings and other family members as well. . . In April of 1995, a 32-year-old man from the Netherlands received the most precious gift of all from his newborn daughter. It was the gift of life. After years of continuous struggle with leukemia, the young father preserved his newborn's cord blood stem cells, which in turn were used to treat his life- threatening disease. This was perhaps one of the most extraordinary gifts ever exchanged between a father and a daughter. Not to mention, a true testament of the power of cord blood."⁷¹</p> <p>"How many samples have been used for transplant from Viacord? Did they all engraft? Eleven of our banked units have been used in transplant—all have successfully engrafted."⁷²</p> <p>"What is the process once the blood center receives my child's cord blood unit? Upon receipt of your baby's cord blood unit, our lab conducts a battery of tests . . . We'll give you the volume collected and</p>

⁶⁹ See Little Decl., Exh. 10.

⁷⁰ See Little Decl., Exh. 9, at § 1.

⁷¹ See Little Decl., Exh. 15.

⁷² See Little Decl., Exh. 16, at page 3.

	<p>the counts of nucleated cells which are the most critical to successful engraftment."⁷³</p> <p>"What needs to be done to retrieve the sample? If your sample is ever needed, just notify Viacord. We will ask you to sign a release form and indicate the name and address of the hospital where your unit will be going. Then Viacord and the other hospital will work out the details for immediate transfer."⁷⁴</p>
a composition comprising human neonatal or fetal hematopoietic stem cells	<p><u>ViaCell Statements:</u></p> <p>"In the early 1980s, Dr. Hal Broxmeyer (now a member of Viacord's Medical Scientific Advisory Board) was instrumental in validating that the blood remaining in the umbilical cord after birth is rich in a precious resource called stem cells. Stem cells are the building blocks of our blood and immune systems and, potentially, the nervous system, skin, bones, heart, endocrine organs and other body tissue. Over the past decade, thousands of cord blood stem cell transplants have been successfully performed worldwide."⁷⁵</p> <p>"Your pregnancy provides an opportunity to do something extraordinary for your baby and your entire family. By choosing to preserve your newborn's cord blood with Viacord, you will preserve your family's chance to potentially use it as part of a treatment therapy for over 40 diseases, including various cancers, genetic diseases, blood disorders and immune system deficiencies."⁷⁶</p> <p>"Umbilical cord blood offers a perfectly natural, controversy-free method of acquiring stem cells. (Even the Pope approves of cord blood banking.) Cord blood offers several advantages over other methods. It's collected in a safe, 5-minute procedure after a baby is born and is painless for both mother and baby. Also, cord blood transplants have a significantly lower rate of graft vs. host disease than bone marrow transplants. Plus, cord blood stem cells are a perfect match for the baby and can potentially be used to treat siblings and other family members as well. . . In April of 1995, a 32-year-old man from the Netherlands received the most precious gift of all from his newborn daughter. It was the gift of life. After years of continuous struggle with leukemia, the young father preserved his newborn's cord blood stem cells, which in turn were used to treat his life- threatening disease. This was perhaps one of the most extraordinary gifts ever exchanged</p>

⁷³ See Little Decl., Exh. 13, at page 1.

⁷⁴ See Little Decl., Exh. 17, at page 1.

⁷⁵ See Little Decl., Exh. 10.

⁷⁶ See Little Decl., Exh. 11.

	between a father and a daughter. Not to mention, a true testament of the power of cord blood." ⁷⁷
derived from the umbilical cord blood or placental blood of a human collected at birth of said human,	<p><u>ViaCell Statements:</u> "Your pregnancy provides an opportunity to do something extraordinary for your baby and your entire family. By choosing to preserve your newborn's cord blood with Viacord, you will preserve your family's chance to potentially use it as part of a treatment therapy for over 40 diseases, including various cancers, genetic diseases, blood disorders and immune system deficiencies."⁷⁸</p> <p>"(Step 1:) Once you have enrolled, you will receive a collection kit to take with you to the hospital when you are ready to deliver. We will also provide your doctor with the materials and training needed for the cord blood collection. (Step 2:) Upon arriving at the hospital, give Viacord's 24-hour on-call service a call so we can review the collection process with your doctor or nurse. . . (Step 3:) After delivering your newborn, your doctor clamps and cuts the umbilical cord then takes your baby out of the birthing area. The collection itself is simple, aseptic, painless and does not interfere with your delivery. . . (Step 4:) Once you've called Viacord to let us know the cord blood was collected, Viacord arranges for a private medical courier to bring your baby's cord blood unit to the nearest airport where it is put on the next flight out to our state-of-the-art long-term storage facility. . . (Step 5:) Upon receipt of your baby's cord blood unit our storage facility conducts the following tests on the cord blood sample that are essential in the event of a potential transplant: the volume collected, the number and viability of nucleated cells, sterility, and the percent of CD34 cells. . . (Step 6:) After testing, your baby's cord blood unit is cryopreserved in cryoprotected blood bags at -196 degrees Celsius (-321 degrees Fahrenheit). . ."⁷⁹</p>
in which the stem cells have been previously cryopreserved,	<p><u>ViaCell Statements:</u> "(Step 1:) Once you have enrolled, you will receive a collection kit to take with you to the hospital when you are ready to deliver. We will also provide your doctor with the materials and training needed for the cord blood collection. (Step 2:) Upon arriving at the hospital, give Viacord's 24-hour on-call service a call so we can review the collection process with your doctor or nurse. . . (Step 3:) After delivering your newborn, your doctor clamps and cuts the umbilical cord then takes your baby out of the birthing area. The collection itself is simple, aseptic, painless and does not interfere with your delivery. . . (Step 4:) Once you've called Viacord to let us know the cord blood was collected, Viacord arranges for a private medical</p>

⁷⁷ See Little Decl., Exh. 15.

⁷⁸ See Little Decl., Exh. 11.

⁷⁹ See Little Decl., Exh. 12, *passim*.

	<p>courier to bring your baby's cord blood unit to the nearest airport where it is put on the next flight out to our state-of-the-art long-term storage facility. . . (Step 5:) Upon receipt of your baby's cord blood unit our storage facility conducts the following tests on the cord blood sample that are essential in the event of a potential transplant: the volume collected, the number and viability of nucleated cells, sterility, and the percent of CD34 cells. . . (Step 6:) After testing, your baby's cord blood unit is cryopreserved in cryoprotected blood bags at -196 degrees Celsius (-321 degrees Fahrenheit). . ."⁸⁰</p>
<p>so as to provide hematopoietic reconstitution.</p>	<p><u>ViaCell Statements:</u></p> <p>"In the early 1980s, Dr. Hal Broxmeyer (now a member of Viacord's Medical Scientific Advisory Board) was instrumental in validating that the blood remaining in the umbilical cord after birth is rich in a precious resource called stem cells. Stem cells are the building blocks of our blood and immune systems and, potentially, the nervous system, skin, bones, heart, endocrine organs and other body tissue. Over the past decade, thousands of cord blood stem cell transplants have been successfully performed worldwide."⁸¹</p> <p>"In the event that your cord blood unit is needed for transplant, Viacord will conduct appropriate testing on both the cord and maternal blood samples and ship the cord blood unit to the appropriate facility upon written request from a physician qualified to perform a stem cell transplant."⁸²</p> <p>"Umbilical cord blood offers a perfectly natural, controversy-free method of acquiring stem cells. (Even the Pope approves of cord blood banking.) Cord blood offers several advantages over other methods. It's collected in a safe, 5-minute procedure after a baby is born and is painless for both mother and baby. Also, cord blood transplants have a significantly lower rate of graft vs. host disease than bone marrow transplants. Plus, cord blood stem cells are a perfect match for the baby and can potentially be used to treat siblings and other family members as well. . . In April of 1995, a 32-year-old man from the Netherlands received the most precious gift of all from his newborn daughter. It was the gift of life. After years of continuous struggle with leukemia, the young father preserved his newborn's cord blood stem cells, which in turn were used to treat his life- threatening disease. This was perhaps one of the most extraordinary gifts ever exchanged between a father and a daughter. Not to mention, a true testament of the power of cord blood."⁸³</p>

⁸⁰ See Little Decl., Exh. 12, *passim*.

⁸¹ See Little Decl., Exh. 10.

⁸² See Little Decl., Exh. 9, at § 1.

⁸³ See Little Decl., Exh. 15.

	<p>"How many samples have been used for transplant from Viacord? Did they all engraft?" Eleven of our banked units have been used in transplant—all have successfully engrafted."⁸⁴</p> <p>"What is the process once the blood center receives my child's cord blood unit?" Upon receipt of your baby's cord blood unit, our lab conducts a battery of tests . . . We'll give you the volume collected and the counts of nucleated cells which are the most critical to successful engraftment."⁸⁵</p> <p>"What needs to be done to retrieve the sample?" If your sample is ever needed, just notify Viacord. We will ask you to sign a release form and indicate the name and address of the hospital where your unit will be going. Then Viacord and the other hospital will work out the details for immediate transfer."⁸⁶</p>
Claim 49 of the '427 Patent	
Claim (Elements in Bold)	Infringement Evidence
A method for storing human neonatal or fetal hematopoietic stem cells derived from the blood, said method comprising cryopreserving human neonatal or fetal blood components	<p><u>ViaCell Statements:</u></p> <p>"(Step 1:) Once you have enrolled, you will receive a collection kit to take with you to the hospital when you are ready to deliver. We will also provide your doctor with the materials and training needed for the cord blood collection. (Step 2:) Upon arriving at the hospital, give Viacord's 24-hour on-call service a call so we can review the collection process with your doctor or nurse. . . (Step 3:) After delivering your newborn, your doctor clamps and cuts the umbilical cord then takes your baby out of the birthing area. The collection itself is simple, aseptic, painless and does not interfere with your delivery. . . (Step 4:) Once you've called Viacord to let us know the cord blood was collected, Viacord arranges for a private medical courier to bring your baby's cord blood unit to the nearest airport where it is put on the next flight out to our state-of-the-art long-term storage facility. . . (Step 5:) Upon receipt of your baby's cord blood unit our storage facility conducts the following tests on the cord blood sample that are essential in the event of a potential transplant: the volume collected, the number and viability of nucleated cells, sterility, and the percent of CD34 cells. . . (Step 6:) After testing, your baby's cord blood unit is cryopreserved in cryoprotected blood bags at -196 degrees Celsius (-321 degrees Fahrenheit). . ."⁸⁷</p>
containing human	<u>ViaCell Statements:</u>

⁸⁴ See Little Decl., Exh. 16, at page 3.

⁸⁵ See Little Decl., Exh. 13, at page 1.

⁸⁶ See Little Decl., Exh. 17, at page 1.

⁸⁷ See Little Decl., Exh. 12, *passim*.

<p>neonatal or fetal hematopoietic stem cells</p>	<p>"In the early 1980s, Dr. Hal Broxmeyer (now a member of Viacord's Medical Scientific Advisory Board) was instrumental in validating that the blood remaining in the umbilical cord after birth is rich in a precious resource called stem cells. Stem cells are the building blocks of our blood and immune systems and, potentially, the nervous system, skin, bones, heart, endocrine organs and other body tissue. Over the past decade, thousands of cord blood stem cell transplants have been successfully performed worldwide."⁸⁸</p> <p>"Your pregnancy provides an opportunity to do something extraordinary for your baby and your entire family. By choosing to preserve your newborn's cord blood with Viacord, you will preserve your family's chance to potentially use it as part of a treatment therapy for over 40 diseases, including various cancers, genetic diseases, blood disorders and immune system deficiencies."⁸⁹</p> <p>"Umbilical cord blood offers a perfectly natural, controversy-free method of acquiring stem cells. (Even the Pope approves of cord blood banking.) Cord blood offers several advantages over other methods. It's collected in a safe, 5-minute procedure after a baby is born and is painless for both mother and baby. Also, cord blood transplants have a significantly lower rate of graft vs. host disease than bone marrow transplants. Plus, cord blood stem cells are a perfect match for the baby and can potentially be used to treat siblings and other family members as well. . . In April of 1995, a 32-year-old man from the Netherlands received the most precious gift of all from his newborn daughter. It was the gift of life. After years of continuous struggle with leukemia, the young father preserved his newborn's cord blood stem cells, which in turn were used to treat his life- threatening disease. This was perhaps one of the most extraordinary gifts ever exchanged between a father and a daughter. Not to mention, a true testament of the power of cord blood."⁹⁰</p>
<p>from the umbilical cord blood or placental blood of a single human collected at the birth of said human,</p>	<p><u>ViaCell Statements:</u></p> <p>"Your pregnancy provides an opportunity to do something extraordinary for your baby and your entire family. By choosing to preserve your newborn's cord blood with Viacord, you will preserve your family's chance to potentially use it as part of a treatment therapy for over 40 diseases, including various cancers, genetic diseases, blood disorders and immune system deficiencies."⁹¹</p> <p>"(Step 1:) Once you have enrolled, you will receive a collection kit to</p>

⁸⁸ See Little Decl., Exh. 10.

⁸⁹ See Little Decl., Exh. 11.

⁹⁰ See Little Decl., Exh. 15.

⁹¹ See Little Decl., Exh. 11.

	<p>take with you to the hospital when you are ready to deliver. We will also provide your doctor with the materials and training needed for the cord blood collection. (Step 2:) Upon arriving at the hospital, give Viacord's 24-hour on-call service a call so we can review the collection process with your doctor or nurse. . . (Step 3:) After delivering your newborn, your doctor clamps and cuts the umbilical cord then takes your baby out of the birthing area. The collection itself is simple, aseptic, painless and does not interfere with your delivery. . . (Step 4:) Once you've called Viacord to let us know the cord blood was collected, Viacord arranges for a private medical courier to bring your baby's cord blood unit to the nearest airport where it is put on the next flight out to our state-of-the-art long-term storage facility. . . (Step 5:) Upon receipt of your baby's cord blood unit our storage facility conducts the following tests on the cord blood sample that are essential in the event of a potential transplant: the volume collected, the number and viability of nucleated cells, sterility, and the percent of CD34 cells. . . (Step 6:) After testing, your baby's cord blood unit is cryopreserved in cryoprotected blood bags at -196 degrees Celsius (-321 degrees Fahrenheit). . ."⁹²</p>
such that the cells remain viable ,	<p><u>ViaCell Statements:</u> "How long can cord blood stem cells be stored? Scientific research has yet to determine the actual length of time these cells can be stored and still be viable. It is known that cord blood stem cells remain viable for many years and possibly decades. So far, the longest time bone marrow stem cells have been frozen and successfully transplanted was eleven years as reported by Dr. Joe Antin in Bone Marrow Transplantation in 1992. Dr. Peter Kobylka of the University of Amsterdam showed viability of cord blood stem cells frozen for 15 years."⁹³</p> <p>"In the event that your cord blood unit is needed for transplant, Viacord will conduct appropriate testing on both the cord and maternal blood samples and ship the cord blood unit to the appropriate facility upon written request from a physician qualified to perform a stem cell transplant."⁹⁴</p> <p>"How many samples have been used for transplant from Viacord? Did they all engraft? Eleven of our banked units have been used in transplant—all have successfully engrafted."⁹⁵</p>
in which said cells are present in an amount	<p><u>ViaCell Statements:</u> "Your baby's cord blood could someday save a life. Your baby's.</p>

⁹² See Little Decl., Exh. 12, *passim*.

⁹³ See Little Decl., Exh. 13, at page 3.

⁹⁴ See Little Decl., Exh. 9, at § 1.

⁹⁵ See Little Decl., Exh. 16, at page 3.

<p>sufficient to effect hematopoietic reconstitution of a human adult.</p>	<p>Your family's. Yours."⁹⁶</p> <p>"Cord blood stem cells are a perfect match for your baby, have a high probability of being a viable match for a sibling and can be potentially be used for parents and grandparents in the treatment of over 40 diseases including a wide range of cancers, genetic diseases, immune system deficiencies and blood disorders."⁹⁷</p> <p>"Umbilical cord blood offers a perfectly natural, controversy-free method of acquiring stem cells. (Even the Pope approves of cord blood banking.) Cord blood offers several advantages over other methods. It's collected in a safe, 5-minute procedure after a baby is born and is painless for both mother and baby. Also, cord blood transplants have a significantly lower rate of graft vs. host disease than bone marrow transplants. Plus, cord blood stem cells are a perfect match for the baby and can potentially be used to treat siblings and other family members as well. . . In April of 1995, a 32-year-old man from the Netherlands received the most precious gift of all from his newborn daughter. It was the gift of life. After years of continuous struggle with leukemia, the young father preserved his newborn's cord blood stem cells, which in turn were used to treat his life- threatening disease. This was perhaps one of the most extraordinary gifts ever exchanged between a father and a daughter. Not to mention, a true testament of the power of cord blood."⁹⁸</p> <p><u>ViaCell's Quality Product Guarantee:</u></p> <p>"If the cord blood stem cells processed and stored by Viacord are used in a hematopoietic stem cell transplant following standard, recognized medical practices and they do not engraft, Viacord will pay \$25,000 to the legal owner of the cells per the Viacord Enrollment Agreement."⁹⁹ (Notably, ViaCell's guarantee explicitly includes transplants to the biological parents of the donor, so long as, the transplanted cord blood does not contain less than 2×10^7 total nucleated cells per kilogram or less than 1×10^5 CD34+ cells per kilogram, is not co-transplanted with supplemental stem cell sources (e.g., additional cord blood, peripheral blood or bone marrow), and does not use experimental procedures, such as, stem cell expansion.¹⁰⁰ Thus, so long as the adult patient is a biological parent of the donor and the transplanted cord blood contains at least 2×10^7 total nucleated cells per kilogram and 1×10^5 CD34+</p>
---	---

⁹⁶ See Little Decl., Exh. 14.

⁹⁷ See Little Decl., Exh. 14.

⁹⁸ See Little Decl., Exh. 15.

⁹⁹ See Little Decl., Exh. 9, at last two pages.

¹⁰⁰ See Little Decl., Exh. 9, at last page.

¹⁰¹ See Little Decl., Exh. 16, at page 3.

cells per kilogram, if the cord blood does not engraft in the adult patient following a standard transplantation procedure, ViaCell is bound by its **Quality Product Guarantee**.)

ViaCell Actual Transplants:

"How many samples have been used for transplant from Viacord? Did they all engraft? Eleven of our banked units have been used in transplant—all have successfully engrafted."¹⁰¹

Scientific Journal Articles/Studies (internal citations omitted):

Harris, D. T., *Cord Blood Banking and Its Potential Clinical Applications*.

"[Q]uestions have been raised as to whether cord blood transplantation would ever be suitable for adult use, or restricted to use in children. To date, the smallest amount of cord blood ever used in a successful transplant has been 43 cc, and the largest patient ever successfully transplanted is now 85 kg. *Thus, it appears that a typical cord blood collection is of sufficient size for use in almost all transplant conditions.*"

Laughlin, M. J., *et al.*, *Hematopoietic Engraftment And Survival In Adult Recipients Of Umbilical-Cord Blood From Unrelated Donors*, New England Journal of Medicine (2001)("Laughlin").

"In summary, the results of this study demonstrate that HLA-mismatched umbilical-cord blood from unrelated donors is a feasible alternative source of hematopoietic stem cells for transplantation in adults."

Umbilical Cord Stem Cell Transplants Should Not Be Limited By Age, The Blue Sheet (Food and Drug Administration), March 5, 2003 ("FDA Blue Sheet").

"Placental cord blood transplant recipient age should not be a factor."

Sanz, G. F., *et al.*, *Standardized, Unrelated Donor Cord Blood Transplantation in Adults with Hematologic Malignancies*, Blood (2001)("Sanz").

"[Cord blood transplantation], despite the low cellular dose infused, is capable of promoting sustained hematopoietic engraftment in most adult recipients."

Gluckman. E., *Current Status of Umbilical Cord Blood Hematopoietic Stem Cell Transplantation*, Experimental Hematology (2000)("Gluckman").

"[R]esults show that [cord blood transplantation] can be a good option for adults."

	<p>Iseki, T., <i>et al.</i>, <i>Unrelated Cord Blood Transplantation in Adults with Hematological Malignancy: A Single Institution Experience</i>, Blood Abstract #2789 (2000)("Iseki"). "[Cord blood transplantation in adults] was comparable to that of standard bone marrow transplantation."</p> <p>Ooi, J., <i>et al.</i>, <i>Unrelated Cord Blood Transplantation for Adults Patients with Advanced Myelodysplastic Syndrome</i>, Blood (2003)("Ooi I"). "[Adult patients] should be considered candidates for [cord blood transplants]."</p> <p>Ooi, J., <i>et al.</i>, <i>Unrelated Cord Blood Transplantation for Adults Patients with De Novo Acute Myeloid Leukemia</i>, Blood (2004)("Ooi II"). (Same as Ooi I.)</p> <p>Long, G. D., <i>et al.</i>, <i>Unrelated Cord Blood Transplantation in Adults Patients</i>, Biology of Blood and Marrow Transplantation (2003)("Long"). "These results suggest that unrelated umbilical cord blood transplantation is a viable option for adult patients."</p> <p>Koh, L-P, <i>et al.</i>, <i>Umbilical Cord Blood Transplantation in Adults Using Myeloablative and Nonmyeloablative Preparative Regimens</i>, Biology of Blood and Marrow Transplantation (2004)("Koh"). "The concern of limited doses leading to a higher risk of primary graft failure in adults is related to the disproportionate difference between the number of nucleated cells in the [umbilical cord blood] graft and the adult body weight, giving rise to relative fewer infused cells per kilogram of the recipient body weight, especially in heavier patients. However, the available data on adult recipients of unrelated [umbilical cord blood transplants] thus far have shown the [umbilical cord blood] contained sufficient numbers of hematopoietic stem cells to achieve engraftment."</p> <p>Moscardo, F., <i>et al.</i>, <i>Unrelated-Donor Cord Blood Transplantation for Adult Hematological Malignancies</i>, Leukemia & Lymphoma (2004)("Moscardo"). "The reported data show that, contrary to initial concerns, [cord blood transplants] can promote engraftment in the majority of adult patients."</p> <p>Barker, J. N., <i>et al.</i>, <i>Rapid and Complete Donor Chimerism in Adult Recipients of Unrelated Donor Umbilical Cord Blood Transplantation After Reduced-Intensity Conditioning</i>, Blood (2003)("Barker"). "[The] data demonstrates that 0-2 antigen mismatched [umbilical cord</p>
--	--

	blood] is sufficient to engraft most adults after reduced-intensity conditioning."
--	--

Appendix C

PharmaStem's Existing Licensees¹⁰²:

1. California Cryobank Stem Cell Services
2. New England Cord Blood Bank
3. Stembanc
4. Cord Partners
5. Cord Blood Family Trust
6. Securacell
7. Alpha Cord
8. Cryobanks International
9. Newborn Blood Banking
10. LifeBank USA
11. CORD
12. CureSource
13. Norton Hospitals/Family Link
14. Hemastem Therapeutics
15. GeneAngel
16. Lifestor

¹⁰² See Little Decl., Exh. 32.